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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,389	12/05/2003	Kevin Smith	SYN-8312	9231
27316 7590 01/22/2008 MAYBACK & HOFFMAN, P.A. 5722 S. FLAMINGO ROAD #232 FORT LAUDERDALE, FL 33330			EXAMINER WOO, JULIAN W	
			ART UNIT 3773	PAPER NUMBER
			MAIL DATE 01/22/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/728,389	Applicant(s) SMITH ET AL.	
	Examiner Julian W. Woo	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-87 is/are pending in the application.
- 4a) Of the above claim(s) 67-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18, 20-66 and 83-87 is/are rejected.
- 7) ☒ Claim(s) 17 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/27/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 39 and 60 are rejected under 35 U.S.C. 102(e) as being anticipated by Biggs et al. (6,599,311). Biggs et al. disclose, at least in figures 8-10 and 24A-24B and in col. 3, lines 44-46; col. 11, lines 21-53; col. 16, lines 39-50; and col. 17, lines 52-66; a combination of a flexible endoscope (e.g., 34) having at least one working channel and a tissue retractor (e.g., 200) including a flexible body (e.g., 35), a retraction device including a head (e.g., 208), a connector (e.g., 206), flexible needles (e.g., 204) of a shape memory material (e.g., nickel-titanium alloys) and including a portion with an arcuate shape; and an actuation device (e.g., 202) connected to a proximal end of the body, where upon actuation, the connector is moved to selectively extend the needles out of the head (see fig. 24B) and withdraw the needles into the head (see fig. 24A).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-10, 12-16, 18, 20-25, 27-36, 38, 55-57, 66, 83-85, and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meeker (2,108,206) in view of Ley (5,514,076). Meeker discloses the invention substantially as claimed. Meeker discloses, at least in the figures and in col. 1, line 51 to col. 2, line 41; a retractor including a rigid body (1); a retraction device for manipulating or grasping an object, where the device has a head (2, 3, or distal portion of 1) connected to the distal end of the body, a connector (4c) movably disposed in the body; two, flexible needles (4a or 4b) of resilient metal; and a removable actuation device (9) connected to the proximal end of the body; where the body has a longitudinal extent, where the head is connected removably or integrally formed (i.e., integrated) with the body; where the head has two

head halves (i.e., the head is symmetrical with respect to a longitudinal axis and can be defined by two halves formed together) and defines tracks (5a), which have track exits (5); where the tracks exits open in a direction at a substantially orthogonal angle to the longitudinal direction, where the track exits are disposed to permit movement therethrough substantially without friction and are disposed on opposing sides of the head, where the surfaces of the tracks guide the needles in a direction substantially orthogonal to a movement direction of the connector (see fig. 4), where the tracks have a shape corresponding to a memory shape of a portion of the needles, where the needles include a substantially linear proximal portion and an arcuate distal portion, where the arcuate shape of the portion is no greater than a circle and greater than a semi-circle (around 4c), where the material of the needles is a pseudo-elastic metal, where the actuation device has a rod (4) removably connected to or is integrally formed with (i.e., integrated with) the connector, where the retractor includes proximal stop (6), where the actuation device has a locking device (12) or an overstroke preventor, where the actuation device is a one-handed actuation device, where the head has an anchoring spike (2), where the actuation device selectively moves an actuator (8), where the needles are sized to control penetration depth into tissues, and where the needles are fixedly connected to the connector. However, Meeker does not disclose the flexible needles are of a shape memory material having a memory shape. Ley teaches, at least in figure 2 and in col. 1, line 509 to col. 2, line 25 and col. 4, line 3 to col. 5, line 19; a retractor needle formed of a shape memory material (e.g., nitinol) having a memory shape. It would have been obvious to one having ordinary skill in the

art at the time the invention was made, in view of Ley, to form the needles in the device of Meeker out of a shape memory material having a memory shape. Such a material would allow the needles to have remarkable shape recovery and to possess a relatively low, predictable, and controllable release force, so that inadvertent excessive force applied by a user, while the needles are in tissue, would cause the needles to release, instead of causing tissue damage to a patient.

Additionally, Meeker or Meeker in view of Ley does not disclose that the two halves of the head are removably connected to one another. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the head from two, separate halves, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

5. Claims 1, 5, 11, 26, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitt (3,754,555) in view of Ley (5,514,076). Schmitt discloses the invention substantially as claimed. Schmitt discloses, at least in the figure and in col. 2, line 47 to col. 3, line 47; a retractor including a flexible body (12 and 14)); a retraction device for manipulating or grasping an object, where the device has a head (16) movably disposed in the body; flexible needles (24) of a resilient material; a connector (at 28), and an actuation device (32) connected to the proximal end of the body, where the needles include a portion of arcuate shape (in the vicinity of 30), where the head includes tracks (26) and track exits (distal end of 26) each having a diameter at least as large as a needle diameter, and where the body includes a coil winding (12) and an

outer jacket (14). However, Schmitt does not disclose the flexible needles are of a shape memory material having a memory shape. Ley teaches, at least in figures 2 and 3 and in col. 1, line 59 to col. 2, line 25 and col. 4, line 3 to col. 5, line 19; needles formed of a shape memory material (e.g., nitinol) having a memory shape. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Ley, to form the needles in the device of Schmitt out of a shape memory material having a memory shape. Such a material is biocompatible and would allow the needles to have remarkable shape recovery and to possess a relatively low, predictable, and controllable release force, so that any inadvertent excessive force applied by a user, while the needles are in tissue, would cause the needles to release, instead of causing tissue damage to a patient.

6. Claims 39-54, 58, 59, 61-65, and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meeker (2,108,206) in view of Ley (5,514,076), and further in view of Green (5,928,137). Meeker in view of Ley discloses substantially as claimed a tissue retractor including a rigid body and retraction device. However, Meeker in view of Ley does not disclose that the retractor is combined with a flexible endoscope having at least one working channel for receiving the body and the retraction device. Green teaches, at least in figures 1 and 5 and in col. 6, lines 49-65; a flexible endoscope having at least one working channel (e.g., 152) for receiving an endoscopic tool. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Green, to include a flexible endoscope with the device of Meeker in view of Ley. A flexible endoscope with at least one working channel would not only

allow access for the device of Meeker in view of Ley to a surgical site, it would also allow diagnosis and imaging of the site, especially where the site has narrow, even tortuous confines.

Allowable Subject Matter

7. Claims 17 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a retractor including, inter alia, a body, a retraction device with a head, a connector, flexible needles, and an actuation device, where the head defines tracks for the needles and has two head halves clamping the needles and a shim disposed between the two head halves.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Response to Amendment

9. The rejection under 35 U.S.C. 112, 2nd paragraph is hereby withdrawn with respect to claim 83.

Applicant's arguments filed on October 29, 2007 and regarding the rejection of claims 39 and 60 and based on the Biggs reference have been fully considered, but they are not persuasive. That is, Biggs indeed discloses, at least in figures 24A and 24B and as pointed out in this and previous Office actions, needles that can be selectively extended out of a head and withdraw the needles into the head.

Applicant's arguments, with respect to the rejections of claims 1-15, 18, 20-38, 40-59, 61-66, and 83-87 and based on the references of Meeker, Ley, Green, and Schmitt, have been fully considered, but are not persuasive.

With respect to arguments regarding the rejection based on Meeker and Ley: The Applicant asserts that one skilled in the art would not be motivated to combine any feature of Ley with Meeker to arrive at the present invention, and that the Examiner did not provide a reason for the combination. The Examiner disagrees. First of all, Meeker and Ley disclose flexible needles used as surgical retractors (i.e., the references are within the same, analogous art), and the Examiner drew only upon Ley's teachings regarding shape memory material for flexible needles. Thus, the combination was put forth to arrive at the present invention, and the reason (or motivation) for combining the references was given in this and the previous Office actions, i.e.: "Such a [shape memory] material would allow the needles to have remarkable shape recovery and to possess a relatively low, predictable, and controllable release force, so that inadvertent excessive force applied by a user, while the needles are in tissue, would cause the needles to release, instead of causing tissue damage to a patient."

Similarly, Schmitt discloses flexible needles for surgical use and tissue penetration; so again, Ley's teachings regarding needles of shape memory material were applied in the combination of Schmitt and Ley, where Ley provides a reason or motivation for the combination.

With respect to arguments regarding the rejection based on Meeker, Ley, and Green: The Applicant was correct in noting the typographical error in item 8 of the Office action of August 14, 2007. That is, claims 39-54, 58, 59, 61-65, and 86 are indeed rejected under 35 U.S.C. 103(a) as being unpatentable over Meeker in view of Ley and Green. However, the Examiner disagrees with the Applicant's argument that the three references cannot be combined to arrive at the present invention. The Examiner agrees with the Applicant that Green does not provide teachings regarding flexible needles. However, Meeker and Ley were combined to arrive at the retraction device as claimed. Green was brought into combination with Meeker and Ley only for Green's teachings regarding a flexible endoscope. Green's teachings regarding a device with jaws were not even considered. The device with jaws, as shown in the figures of Green, is presented only as one example of a surgical tool usable with the endoscope. In fact, Green teaches various, elongate surgical tools that can be combined with the flexible endoscope. With this teaching, the surgical tool of Meeker in view of Ley is combined with the endoscope of Green to arrive at the present invention without improper hindsight.

In response to Applicant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that

any judgment on obviousness is in a sense necessarily a reconstruction base upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

January 16, 2008